Effect of Kampo treatment on chronic viral hepatitis on the basis of traditional diagnosis

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Abstract

We investigated the effect of Kampo treatment on 47 patients with chronic viral hepatitis on the basis of traditional diagnosis. The number of patients with hepatitis B and C were 8 and 39, respectively. An improvement in serum alanine aminotransferase (ALT) was observed in 75 % of hepatitis B patients and 44 % of hepatitis C patients after six months of treatment. Symptoms such as easy fatigability and general malaise were improved in 90 % of the patients. Comparing the prognosis of 18 hepatitis C patients treated for more than 3 years with reports on the natural course of the disease following a mean 8.8 years after their first visits, the rate of liver cirrhosis was lower, but the rate of hepatocellular carcinoma and the rate of normalization of liver function were similar. Among the major prescriptions used in this investigation was one that included Bupleuri Radix. Many hepatitis C patients showed a good initial response, but their condition later changed to one indicating prescriptions corresponding to Ki-deficiency. Thus, two kinds of prescriptions could display their effectiveness at different stages of hepatitis C.

Following six months of administration of Hochu-ekki-to (補中益気湯; a typical prescription corresponding to Ki-deficiency) to 20 patients with hepatitis C, an improvement of transaminases was observed in the group with a higher Ki-deficiency score, but not in the group with the lower score.

These finding were thought to be important for the design of a prospective control study while making the best use of traditional medicine.

Key words Chronic viral hepatitis, Hochu-ekki-to(Bu-Zhong-Yi-Qi-Tang), Prescriptions containing Bupleuri Radix, Prescriptions corresponding to Ki-deficiency.

Abbreviations Alanine aminotransferase, ALT ; Aspartate aminotransferase, AST ; Dai-saiko-to (Da-Chai-Hu-Tang), 大柴胡湯; Hochu-ekki-to (Bu-Zhong-Yi-Qi-Tang), 補中益気湯; Inchinko-to (Yin-Chen-Hao-Tang), 茵蔯蒿湯; Kami-shoyo-san (Jia-Wei-Xiao-Yao-San), 加味逍遙散: Keishi-bukuryo-gan (Gui-Zhi-Fu-Ling-Wan), 桂枝茯苓丸; Ki-deficiency score, 気虚スコア, KS ; Oren-gedoku-to (Huang-Lian-Jie-Du-Tang), 黄連解毒湯; Prescriptions containing Bupleuri Radix, 柴胡剤, PB ; Prescriptions corresponding to Ki-deficiency, 補気剤, PK ; Prescriptions corresponding to Oketsu syndrome, 駆瘀血剤, PO ; Saiko-ka-ryukotsu-borei-to (Chai-Hu-Jia-Long-Gu-Mu-Li-Tang), 柴胡加竜骨牡蛎湯; Saiko-keishi-kankyo-to (Chai-Hu-Gui-Zhi-Gan-Jiang-Tang), 柴胡桂枝乾姜湯; Saiko-keishi-to (Chai-Hu-Gui-Zhi-Tang), 柴胡桂枝湯; Shigyaku-san (Si-Ni-San), 四逆散; Sho-saiko-to (Xiao-Chai-Hu-Tang), 小柴胡湯; Toki-shakuyaku-san (Dang-Gui-Shao-Yao-San), 当帰芍薬散.

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I. Introduction

The number of patients with chronic hepatitis in our country are said to be about 1.2 million and they consists from 20 % type B and 80 % type C.[1] Recently, interferon treatment for chronic viral hepatitis has achieved significant success, but at the same time, limitations of its effect and some adverse reactions have become apparent. It has become clear that interferon treatment can eliminate the virus in no more than 30 % of the patients and improve liver dysfunctions without completely clearing of the virus in only about 15 %. It is also widely believed that it is difficult to raise the healing rate of hepatitis B by the use of 28 times doses of interferon, the dosage rate presently recognized by the national health insurance system.[2] Patients not respond to interferon or those not qualifying are usually treated with Glycyrrhizin or Ursodesoxycholic acid. However, these medicines are known to have no anti-viral effect and are limited to improving transaminase levels.[3] Kampo medicines are now being viewed as hopeful agents in the treatment of this disease.

Recently, the safety and effect of the use of Kampo prescriptions for many of the illnesses in modern western medicine have been receiving attention following the report that interstitial pneumonia was a possible adverse effect of Sho-saiko-to (小柴胡湯).[4] The importance of way of the traditional diagnosis ("Sho") in the use of Kampo prescriptions has come to be widely described even in package insert drug information pamphlets of Kampo prescriptions. "Sho" is judged comprehensively by a complex of subjective and objective symptoms at a certain point of illness. Although Kampo medicines have been considered to be most effective when used on "Sho", reports on chronic hepatitis based on large patient populations have been rare.[5,6] The process of "Sho" is generally complicated, but it can be quite simple in some diseases such as when Bakumondo-to is indicated for the dry cough of patients with acute bronchitis. However, in the case of patients with chronic hepatitis, there are no characteristic symptoms with mutual indications for the condition in both modern western medicine and "Sho". We need to accumulate more information about "Sho" in this disease for the purpose of designing a prospective control study while making the best use of traditional medicine. The aim of this study is to investigate the Kampo prescriptions to be used on the basis of traditional diagnosis, their effect on liver dysfunction, and to clarify some aspects of "Sho" in regard to this disease.

II. Effect of Kampo treatment on chronic hepatitis B

1) Short-term effect

Eight patients with chronic hepatitis B were enrolled in this study. They visited our hospital between October 1979 and March 1996 and were administered Kampo medicines for more than six months, based on the principles of traditional diagnosis. They consisted of 3 males and 5 females, aged 44.9 ±10.2 years (mean±S.D.), and their treatment period was 4.5±4.6 years. Their serum levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) were 119±72 KU and 100±66 KU, respectively. Three patients were intolerant to interferon. Regular injections of a drug containing Glycyrrhizin to one patient were continued even after the administration of Kampo medicines, but no additional treatment with western medicines was done within six months after the treatment.

The prescriptions adopted in this study were selected according to traditional diagnosis based on the important points listed in Table I.[7] Medicinal plants comprising these prescriptions are shown in Table II.

Retrospective assessment of the effect was carried out in December 1996. Three patients had continued to attend our hospital, and 5 patients dropped out during the course of treatment. Evaluation of these discontinued patients was made mainly based on progress notes, as well as partly through questionnaires or by telephone.

The method for ALT and AST was changed from the Karmen method to the method recommended by JSCC in April 1994, and the figures after the change were divided by the indices 1.44 and 1.18, respectively.

a) Effect on transaminase levels (Table III)

The effect of Kampo medicines was estimated by the changes of serum ALT levels after six months of

Table I Characteristic signs and symptoms indicating each prescription

1) Prescriptions containing Bupleuri Radix	
Sho-saiko-to	thoraco costal distress, a red tongue with thick fur and sticky saliva, partly anorexia and shoulder stiffness are common in this group
Dai saiko to	constipation, tension of abdominal rectus muscle
Saiko-ka ryukotsu borei to	insomnia, palpitation, mental instability
Shigyaku-san	cooling extremities, tension of abdominal rectus muscle
Saiko-keishi-to	easy to sweat, tension of abdominal rectus muscle
Saiko keishi kankyo to	weak constitution, thirsty, cold feet, sweating of the head and neck
Oren-gedoku-to	feeling of uprising heat, red face, restlessness, insomnia, irritability, tendency for hemorrhage, pruritus
2) Prescriptions corresponding to Ki deficiency	
Hochu-ekki to	general fatigue, lack of will power, easy fatigability, sleepiness during the day, loss of appetite, edema of tongue, weak pulse of the radial artery and organ ptosis
3) Prescriptions corresponding to Oketsu syndrome	
Keishi-bukuryo-gan	dark-rimmed eyes, livid gingiva and tongue, resistance tender on pressure of the para-umbilical region, hemorrhoids and dysmenorrhea are common in this group, feeling of uprising heat and cooling of the legs, no constipation
Toki-shakuyaku san	pale face, dizziness and cooling of the extremities
Kami-shoyo-san	marked fatigue, restlessness, fear, insomnia, irritability, sweating, headache, dizziness
4) Prescriptions containing Artemisiae Capillari Spica	
Inchinko to	constipation, urticaria, jaundice, dry mouth and a feeling of fullness in the upper abdomen

Table II Medicinal plants composing of main Kampo prescriptions for chronic hepatitis

	BR	GIR	SR	ZF	GiR	CC	PR	ZR	ZSR	PT	others
Sho saiko-to	○	○	○	○	○			○		○	
Saiko keishi to	○	○	○	○	○	○	○	○		○	
Saiko-keishi kankyo to	○	○	○			○			○		OT TR
Hochu ekki to	○	○		○	○				○		ANP AnR AsR AtR CiR
Keishi-bukuryo gan						○	○				H MC PS
Inchinko to											ACS GF RR

(Abbreviations) Artemisiae Capillari Spica, 茵蔯蒿, ACS ; Aurantii Nobilis Pericarpium, 陳皮, ANP ; Angelicae Radix, 当帰, AnR ; Atractylodis Rhizoma, 白朮, AtR ; Astragali Radix, 黄耆, AsR ; Bupleuri Radix, 柴胡, BR ; Cinnamomi Cortex, 桂枝, CC ; Cimicifugae Rhizoma, 升麻, CiR ; Gardeniae Fructus, 山梔子, GF ; Ginseng Radix, 人参, GiR ; Glycyrrhizae Radix, 甘草, GlR ; Hoelen, 茯苓, H ; Moutan Cortex, 牡丹皮, MC ; Ostreae Testa, 牡蛎, OT ; Paeoniae Radix, 芍薬, PR ; Persicae Semen, 桃仁, PS ; Pinelliae Tuber, 半夏, PT ; Rhei Rhizoma, 大黄, RR ; Scutellariae Radix, 黄芩, SR ; Trichosanthis Radix, 栝楼根, TR ; Zizyphi Fructus, 大棗, ZF ; Zingiberis Rhizoma, 生姜, ZR ; Zingiberis Siccatum Rhizoma, 乾姜, ZSR

administration ; cases with ALT decrease over 50 % were judged as "marked improvement", cases with ALT decrease from 21 % to 50 % as "mild improvement", cases with ALT decrease within 20 % or fluctuating within normal range as "unchanged", and cases with ALT increase over 20 % as "aggravation". According to these criteria, among the 8 patients, marked improvement was seen in 5 (63 %), and mild improvement, unchanged and aggravation in one each (13 %).

Serum ALT levels decreased from 119±25 KU (mean±S.E.) to 46±11 KU, statistically significant, after 6 months of treatment. Serum AST levels also had a decreasing tendency from 99±23 KU to 47± 8 KU, but no statistical significance.

b) Investigation of Kampo medicines administered on the basis of traditional diagnosis

Effective Kampo prescriptions for the patients were Saiko-keishi-to in 2, Hochu-ekki-to in 2, Dai saiko-to in one and Sho-saiko-to in one. Used

Table III The effect of Kampo prescriptions assessed after 6 months of treatment (short-term study)

Type of hepatitis	B				C			
Assessment	marked lmprovement	mild	unchan-ged	aggra-vation	marked lmprovement	mild	unchan-ged	aggra-vation
Total number of patients	5	1	1	1	7	10	12	10
Sho-saiko-to	1	0	0	0	1	0	0	1
Saiko-keishi-to	2	0	1	0	0	1	0	0
Saiko-keishi-kankyo-to	0	0	0	1	1	3	4	1
Other PB	2	0	0	0	1	3	2	2
Hochu-ekki-to	1	1	0	0	4	2	3	2
Other PK	0	0	0	0	0	0	1	2
Keishi-bukuryo-gan	3	1	0	0	2	0	4	3
Other PO	0	0	1	0	0	2	1	0
Inchinko to	2	0	0	0	2	0	1	0

Prescriptions containing Bupleuri Radix, 柴胡剤, PB ; Prescriptions corresponding to Ki-deficiency, 補気剤, PK ; Prescriptions corresponding to Oketsu syndrome, 駆瘀血剤, PO

together with these prescriptions, Keishi-bukuryo-gan and Inchinko-to were effective in 4 and 2, respectively.

c) Effect on symptoms indicating for Ki-deficiency.

We investigated the change of symptoms indicating Ki-deficiency such as general malaise and easy fatigability during the initial six months by analysis of progress notes and questionnaires.

Five of the 8 patients had such symptoms indicating Ki-deficiency, and 4 of them showed improved symptoms.

2) Long-term effect

The patients were the same as in the short-term study (Table IV). We estimated the long-term effect on hepatitis B patients by normalization of serum ALT and seroconversion.

Three of the 5 patients with positive HBeAg underwent seroconversion, which was recognized at six months, two years and four months, and two years and ten months of Kampo treatment, respectively. One patient discontinued our treatment and the fifth progressed to liver cirrhosis in spite of continuing treatment. Liver dysfunction of the three patients with negative HBeAg improved within one year after beginning the treatment.

The effect of Kampo medicines mainly used by

Table IV Long-term results of patients with chronic hepatitis B treated by Kampo medicine for more than half a year

age	sex	HBeAg	ALT	treatment period	normalization of ALT	seroconversion	Kampo prescription
		(CI)	(KU)	(year)	(year)	(year)	
30*	M	5.3	49	1.0	0.5	0.5	Saiko-keishi-to+Keishi-bukuryo-gan+Inchinko-to
43*	M	4.3	170	10.4	1.6	2.3	Saiko-keishi-to+Keishi-bukuryo-gan
30*	F	9.8	144	2.8	0.5	2.8	Hochu-ekki-to
44*	M	429.9	102	0.4	unchanged		Saiko-keishi-to+Kami-shoyo-san (extract)
52*	F	3.7	31	8.8	aggravation		Saiko-keishi-kankyo-to
51	F	−	251	10.7	0.9		Sho-saiko-to+Inchinko-to+Keishi-bukuryo-gan (pills)
53*	F	−	133	0.9	0.4		Dai-saiko-to
56	F	−	73	0.7	0.7		Hochu-ekki-to+Keishi-bukuryo-gan (pills)

*Liver biopsies showed CAH

prescriptions containing Bupleuri Radix (PB) and prescriptions corrsponding to Oketsu syndrome (PO) on hepatitis B is already known.[8,9] Even in this study, 3 of 5 patients achieved seroconversion within the initial three years of treatment. This result shows, despite the small number of patients, that this rate may exceed the reported 3~5 % per year of the natural rate of seroconversion.[10]

III. Effect of Kampo treatment on chronic hepatitis C

1) Short-term effect

Thirty-nine patients were enrolled in this study. They visited our hospital during the same period as the hepatitis B patients and were administered Kampo medicines for six months similaly, based on the principles of traditional diagnosis. They consisted of 20 males and 19 females, aged 56.1±12.2 years, with a treatment period of 4.8±4.7 years (mean±S.D.). Their serum levels of ALT and AST were 90±63 KU and 82±61 KU, respectively. Six patients were intolerant to interferon. Regular injections of a drug containing Glycyrrhizin to two patients were continued even after the administration of Kampo medicines, but no additional treatment with western medicines was done within six months after the treatment. Eighteen patients had histories of blood transfusion. The management protocol was the same as for the hepatitis B patients.

Twenty-two patients continued to attend our hospital, and 9 patients had dropped out during the course of treatment in December 1996. Evaluation of these discontinued 9 patients was made mainly based on progress notes, questionnaires or by telephone, the same as for the hepatitis B patients.

a) Effect on transaminase levels (Table III)

According to the same criteria as for hepatitis B, the effect of Kampo medicines on the 39 hepatitis C patients was estimated as marked improvement in 7 (18 %), mild improvement in 10 (26 %), unchanged in 12 (31 %) and aggravation in 10 (26 %). Therefore, the short-term effect was superior in hepatitis B compared to hepatitis C.

There was no statistical significance in the levels of ALT and AST between before and after 6 months of treatment.

b) Investigation of Kampo medicines administered on the basis of traditional diagnosis.

The effective Kampo prescriptions in patients with hepatitis C were Hochu-ekki-to in 4, Saiko-keishi-kankyo-to in 2, Sho-saiko-to in one and Saiko-keishi-to in one. By combined use with these prescriptions, Keishi-bukuryo-gan and Inchinko-to were effective in 2 and 2 patients, respectively.

c) Effect on symptoms indicating Ki-deficiency.

Thirty-one of the 39 patients (79 %) had symptoms indicating Ki-deficiency. There was no difference in the effect on ALT levels between with or without these symptoms. Twenty-seven patients (87 %) showed improved symptoms.

2) Long-term effect

The long-term effect was evaluated in 18 patients following more than three years of Kampo treatment. They consisted of 9 males and 9 females, aged 57±11 years and their treatment period was 8.8±4.3 years. Their ALT and AST levels were 94±60 KU and 87±66 KU, respectively. We investigated the liver function of 18 patients throughout the course of receiving treatment for more than three years. The serum ALT levels of 16 of them were measured every half year up to three years after the start of treatment (Fig. 1). It was 94±16 KU (mean±S.E.) before treatment began and gradually decreased to 59±12 KU after 2.0 years, 62±10 KU after 2.5 years and 58±9 KU after 3.0 years. The changes were statistically significant from two years after the beginning of treatment.

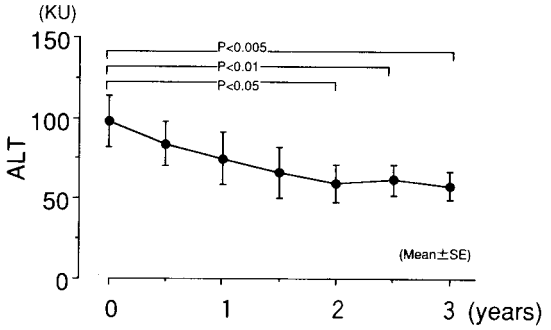

Fig. 1 Serum ALT level in patients with hepatitis C with more than three years by treatment of Kampo medicines. This analysis was done with 16 of the 18 patients, because two of them were lacking one or two of the measurement points of serum ALT. Statistical analysis was performed by the Friedman test.

Table V Long-term results of patients with hepatitis C following more than three years of Kampo treatment

liver functions	cases	sex m/f	initial ALT	treatment period	compli -cations	PB/PK beginning at investigation
stabilization	7	2/5	78(KU)	8.0(year)	−	6/0 → 1/5
recurrence	7	5/2	77	10.8	LC1 HCC3	5/2 → 3/4
instability	4	2/2	150	6.6	LC2+	2/1 → 1/2
total	18	9/9	94	8.8		13/3 → 5/11

HCC, Hepatocellular carcinoma ; LC, Liver Cirrhosis ; PB, Prescriptions containing Bupleuri Radix, 柴胡剤 ; PK, Prescriptions corresponding to Ki deficiency, 補気剤.

In addition, we also classified the long-term results of the 18 patients into three categories---stabilization, recurrence and instability---under the standard for stable liver function that ALT levels stayed below double the value of the normal upper limit, platelet counts were normal, and there was no abnormality in the shape of the liver.

According to these criteria, the long-term results of the 18 patients showed stabilization in 7 patients, recurrence in 7 and instability in 4 (Table V). The ALT levels of the 4 unstable patients were 150±80 KU (mean±S.D.), showing a distinct tendency to be higher than 78±44 KU of the 7 stable patients and 77±47 KU of the 7 recurrent patients. Two of the unstable patients who were diagnosed as liver cirrhosis at a mean treatment period of 6.6 years died two years after discontinuation of Kampo treatment. In the 7 recurrent patients, liver cirrhosis in one and hepatocellular carcinoma in 3 were revealed at a mean treatment period of 10.8 years. On the other hand, the 7 stable patients at a mean treatment period of 8.0 years had neither liver cirrhosis nor hepatocellular carcinoma. Total long-term complications of the 18 patients were liver cirrhosis in 3 (17 %) and hepatocellular carcinoma in 3 (17 %) and one patient (6 %) had normalization of liver function after an average period of 8.8 years of treatment.

In general, hepatitis C cannot heal naturally, but serum ALT levels of most of our patients after more than two years of treatment, although not reaching normal range, had apparently decreased. Some reports about the natural course of chronic hepatitis C after the same period indicated cirrhotic rates of 32 % (49 out 155 ; Inoue *et al.*[11]), 30 % (20 out of 66 ; Nakano *et al.*[12]) and 33 % (32 out of 98 ; Yatsumata *et al.*[13]). These figures were much higher than our 17 %, but this comparison may lack in validity because of our small patient population and incomplete follow-up by liver biopsies. Nevertheless, it appears that Kampo prescriptions on the basis of traditional medicine might decrease the cirrhotic rate from chronic hepatitis C.

Otherwise, the rates of hepatocellular carcinoma and normalization of liver function were similar to those of the reports of the natural course of chronic viral hepatitis with the same follow-up period.[11 13] Considering the report by Oka *et al.* that the five-year administration of only Sho-saiko-to prevented the development of hepatocelular carcinoma in cirrhotic patients without HBs antigen,[14] we have to recognize that our treatment neets to be improved in order to achieve similar results.

In our study Inchinko-to remarkably inproved liver dysfunction in 4 of 5 patients, together with hepatitis B patients. This prescription consists simply of Gardeniae Fructus, Artemisiae Capillari Spica and Rhei Rhizoma. Its additive effect with PB or prescriptions corresponding to Ki-deficiiency (PK) is especially noteworthy. Its indication might be broader, as patients who responded to Inchinko-to did not necessarily have jaundice and itching, said to be the traditional indications for its use. The more frequent use of this prescription might increase the effect of our treatment of chronic hepatitis.

Retrospective investigation of the Kampo medicines used for the hepatitis C patients in our series showed that PB and PK had been initially used in 13 and 3, but this had changed to 5 and 11 at the time of

the present study. This pattern of changing prescriptions from PB to PK was mostly seen in stable cases with the best prognoses. Considering Yamauchi's report that many patients with liver cirrhosis respond to PK,[6] there might be a tendency for patients with hepatitis C to gradually become to respond to PK before progressing to liver cirrhosis. The favorable effect of PK on hepatitis C was recently reported,[15,16] but we might consider that this effect is exhibited mostly at the relatively advanced stage of the disease.

IV. Effect of Hochu-ekki-to on patients with chronic hepatitis C

Hochu-ekki-to, as described earlier, was the most frequently effective Kampo medicine for patients with chronic hepatitis C. Although there have been no reports to date about any relationship between Ki-deficiency and improvement of liver dysfunction following the administration of Hochu-ekki-to, this prescription is one of those used for patients with Ki-deficiency in the usual way of traditional medicine. Then, to determine the relationship between Ki-deficiency and liver dysfunction, by using the diagnostic score of Ki-deficiency proposed by Terasawa[3] (Table VI), we studied the effect of Hochu-ekki-to on transaminase levels of hepatitis C patients.

We administered this prescription as a decoction to 20 patients with hepatitis C for six months. These patients consisted of 9 males and 11 females, and were 58.8±13.4 years. Their ALT and AST levels were 107±71 KU and 81±48 KU, respectively. Following the administration of this prescription, serum ALT levels had a tendency to decrease overall in spite of the lack of statistical significance, but serum AST levels did not change.

Then, by dividing the subjects into two groups, one with more than a median Ki-deficiency score of 25 points, the other with 25 points or less, the serum ALT level decreased in the high group with statistical significance, but did not change in the group with 25 points or less (Fig. 2). Similarly, the serum AST level decreased with statistical significance in the former group but showed no change in the latter. These results suggest that hepatitis C patients presenting Ki-deficiency symptoms such as general malaise, asthenia and easy fatigability could respond to this prescription. The relationship between the Ki-deficiency score and the state of liver dysfunctions will require investigations.

Table VI Diagnostic score of Ki-deficiency[3]

symptom	point
general physical fatigue	10
lack of will power	10
easy fatigability	10
sleeping during the day	8
loss of appetite	4
easily acquiring diseases	8
being easily frightened	4
dull eyes, feeble voice	6
tongue faint red, edema	8
pulse of deficiency-type	8
markedly diminished abdominal tension	8
organ ptosis	10
reduced tension of the lower abdomen	6
tendency of diarrhea	4

A total count of more than 30 points indicates Ki deficiency. Mild symptoms are assigned half of their point value.

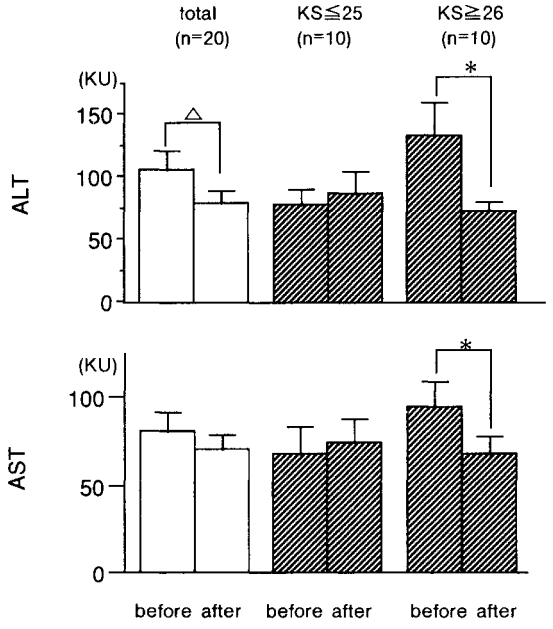

Fig. 2 Changes of serum ALT and AST levels in patients with hepatitis C during the administration of Hochu-ekki-to for six months
KS, Ki-deficiency score. *; $p<0.05$, before vs. after the treatment (Statistical analysis was performed by Wilcoxon signed-ranks test).

V. Conclusion

We studied the effect of Kampo treatment on chronic viral hepatitis on the basis of traditional diagnosis.

Subjective symptoms such as general malaise and easy fatigability were improved in most patients with hepatitis B or hepatitis C after six months of treatment.

Following long-term treatment, the seroconversion rate in hepatitis B patients may exceed the natural rate. Compared with reports on the natural course, there is a possibility that Kampo prescriptions on the basis of traditional medicine might decrease the cirrhotic rate from chronic hepatitis C. However, the rate of hepatocellular carcinoma and normalization of liver function were similar to those of the natural course. Many chronic hepatitis patients overall responded to PB, but patients with hepatitis C gradually became to respond to PK.

Following six months of administration of Hochu-ekki-to to hepatitis C patients, improvement of transaminase levels was observed in the higher Ki-deficiency score group, but not in the lower group.

These results suggest that traditional diagnosis for the effective use of Kampo treatment was very important for treating patients with chronic hepatitis. These finding were thought to be useful for the design of a prospective control study as well as to profit from the benefits of traditional medicine.

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和文抄録

慢性B型およびC型肝炎47症例(B型8例，C型39例)に対する和漢薬随証治療の効果について検討した。治療6ケ月時の血清ALT値の改善はB型75％，C型44％であった。易疲労，倦怠感などの症状は両型とも約9割の症例で改善された。治療期間3年以上の18例について平均8.8年の時点で自然経過報告と比較してみると肝硬変への移行率は少なかったが肝細胞癌の発生頻度と臨床的治癒の率は同等であった。使用方剤は両型ともに柴胡剤が多いが，C型の証は柴胡剤で始まり肝障害の進行とともに補剤に変化する傾向を認めた。柴胡剤と補剤には使用すべき時期に相違があるように考えられた。そこで別のC型20例に対して補中益気湯を6ケ月投与したところ，トランスアミナーゼ値は気虚スコア高値群で低下したが，スコア低値群においては変化しなかった。これらの知見を活かしたcontrol studyを企画していく上で重要と考えられた。

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